2. Non-Technical Abstract

Patients with cancer of the prostate that have localized disease are typically divided in to two categories. These categories are favorable and unfavorable localized disease depending on the level of prostate specific antigen (PSA, a protein produced only by prostate cells), a score based on the histology of the tumor (Gleason" score) and clinical tumor staging. For patients in the favorable category surgery or radiation therapy may be chosen as standard of care. Gene therapy will be added to standard of care radiation for the group of favorable patients choosing radiation therapy. For patients with unfavorable local disease that are not undergoing surgery the standard of care is hormonal therapy plus radiation. This protocol will add gene therapy to hormonal and radiation therapy for that group of patients with unfavorable local disease. The gene therapy consists of an adenovirus (cold virus) that has been engineered to carry a Herpes virus gene that will make infected cells susceptible to a drug called Vanciclovir. For patients with favorable localized disease he adenoviral vector (vehicle) will be injected directly into the prostate gland. two days prior to beginning radiation and once again 15 days later. For patients with unfavorable disease characteristics the gene therapy will begin with one injection at the time of hormone therapy initiation and two additional treatments in conjunction with the radiation therapy.

Tumor biopsies will be performed during treatment. PSA tests, digital rectal exams, and toxicity profiles will also be evaluated during treatment

Fifty patients in each group will be required and it is estimated the study will take approximately three years to complete.